510(k) SUMMARY

ThRevo® Anchor, Disposable Driver, Hi-Fi™ Sutures

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K073481.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

JAN - 7 2008

Joy Lovett
Regulatory Affairs Specialist
(727) 399-5137 Telephone
(727) 399-5264 FAX

C. Device Name

Trade Name: ThRevo® Anchor, Disposable Driver, Hi-Fi Sutures

Common Name: Suture Anchor

Classification Name: Screw, Fastener, Fixation, Nondegradable, Soft Tissue

Proposed Class/Device: Class II

Product Code: MBI

D. Predicate/Legally Marketed Devices

510(k) Name	Classification Panel	Classification Name	510(k) #	Owner
Super Revo Herculine Suture Anchor	Orthopedic	Screw, Fastener, Fixation, Nondegradable, Soft Tissue 21 CFR 888.3040	K041713	Linvatec Corporation

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E. Device Description

The ThRevo® Anchor, Disposable Driver, Hi-Fi™ Sutures is a titanium suture anchor implant pre-threaded with three (3) distinct non-absorbable #2 ultra high molecular weight polyethylene sutures (white, blue and white striped, black and white striped). The design requires no pre-drilling and can be inserted by hand into the bone with the accompanying disposable driver. The device is substantially equivalent in design, performance specifications, function and intended use to the Super Revo Hi-Fi Suture Anchor. The design of the implant has not been modified.

The only difference between the ThRevo Anchor, Disposable Driver, Hi-Fi Sutures and the Super Revo with Hi-Fi is the addition of the third Hi-Fi suture. This modification introduces the use of black nylon 6.6 as a marker for the black cobraid, similar to the blue polypropylene for the blue cobraided suture.

The ThRevo Anchor, Disposable Driver, Hi-Fi Sutures is provided preloaded onto a disposable driver with a stainless steel shaft and ABS handle. It is supplied sterile and single use.

This modification does not affect the device's intended use, fundamental scientific technology or performance specifications.

F. Intended Use

The ThRevo Anchor, Disposable Driver, Hi-Fi Sutures is intended to be used for rotator cuff repairs in the shoulder either arthroscopically or in a mini-open technique.

G. Technological Characteristics

The ThRevo Anchor, Disposable Driver, Hi-Fi Sutures is identical to the predicate device cleared in the original submissions except for the addition of a third polyethylene suture – Super Revo with Hi-Fi. This modification does not affect the device's intended use or performance specifications in a manner that raises any new issues regarding safety and effectiveness.

H. Substantial Equivalence

The ThRevo Anchor, Disposable Driver, Hi-Fi Sutures is substantially equivalent in intended use, design and technological characteristics to the below listed system.

510(k) Name	510(k) #	Owner
Super Revo Herculine Suture Anchor	K041713	Linvatec Corporation

Testing conducted prior to product release assures that the new device does not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

ConMed Linvatec
% Ms. Joy Lovett
Regulatory Affairs Specialist
11311 Concept Boulevard
Largo, Florida 33773

Re: K073481
Trade/Device Name: ThRevo® Anchor, Disposable Drive, Hi-Fi™ Sutures
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: December 3, 2007
Received: December 11, 2007

Dear Ms. Lovett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073481

Device Name: ThRevo® Anchor, Disposable Driver, Hi-Fi™ Sutures

Indications for Use:

The ThRevo® Anchor, Disposable Driver, Hi-Fi™ Sutures is intended to be used for rotator cuff repairs in the shoulder either arthroscopically or in a mini-open technique.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE If NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073481